



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Ani Hwong  
President  
Taiwan AN I Co., Ltd.  
No. 1 Been Ting  
Been-Tsuoh Village  
Taiwan, R.O.C.

**AUG 21 2001**

Re: K010094  
Trade/Device Name: A & I Wheelchairs  
Regulation Number: 890.3850  
Regulatory Class: I  
Product Code: IOR  
Dated: January 9, 2001  
Received: January 11, 2001

Dear Mr. Hwong:

This letter corrects our substantially equivalent letter of February 15, 2001 regarding the name and address of the applicant.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

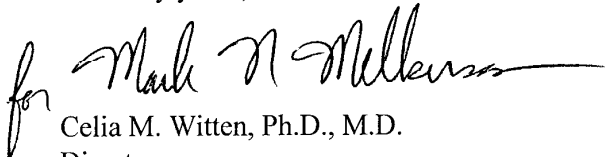
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Ani Hwong

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Miller", with a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

INTENDED USE

510(k) Number (if known): N/A

Device Name: A & I Wheelchairs

Indications for Use:

A & I wheelchairs are intended to be used to provide mobility to persons restricted to a sitting position.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

*for Mark A. Milburn*

(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K010094